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(54) Abstract Title
Dry powder nebuliser

(57) A piston 4 of a dry powder nebuliser 1 slides in a bore 3. An inlet port 6 connects a powder chamber 5 with the bore 3, and an outlet port 15, spaced along the bore 3 from the inlet port 6, connects the bore 3 with atmosphere. A one-way valve 7 is associated with the inlet port 6. Upon moving the piston 4 in the bore 3 in a first direction, powder in the chamber 5 is drawn into the bore 3 through the inlet port 6. Upon moving the piston 4 in the bore 3 in a second, opposite direction, powder drawn into the bore 3 is entrained with air in the bore 3 and forced past the piston 4 to the outlet port 15, from where it exits the bore 3. Clearance is provided between the piston 4 and the bore 3, to allow a small amount of lateral movement of the piston 4 as it travels through the bore 3. This provides a particularly effective action, in that the powder is dispensed in a fine and uniform cloud.

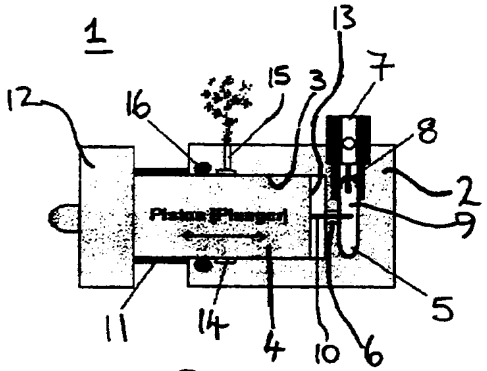

FIG.1

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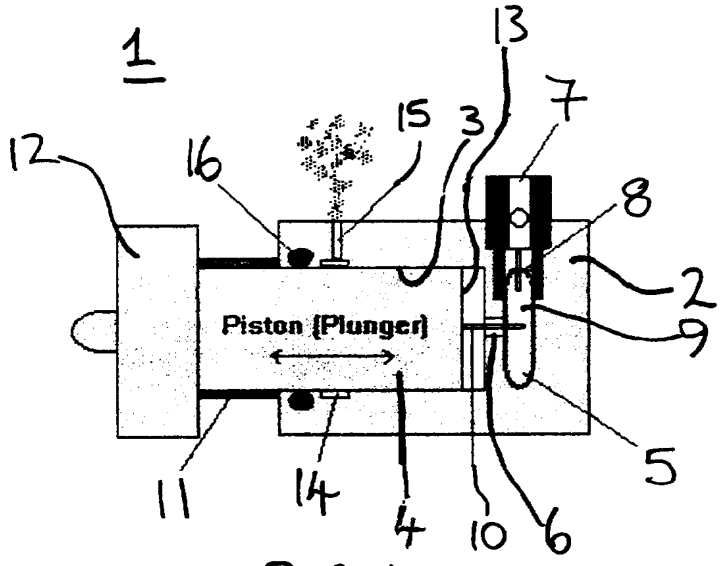

FIG. 1

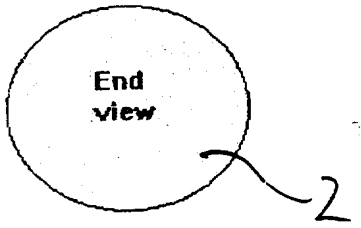

FIG. 2

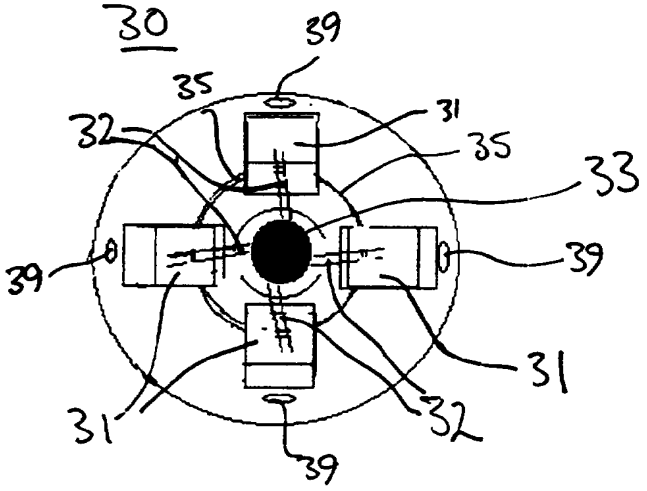

FIG. 3

NEBULISERS

This invention relates to dry powder nebulisers - that is, devices for dispensing a dry powder in the form of a cloud of very fine particles.

Many types of nebulising devices have been proposed. Some of these comprise large and bulky apparatus designed for use in situ - for example, in hospitals and/or by the bedside. They are used to deliver drugs that are required to be administered in a dry particulate form. There is a need, however, to provide a nebuliser which may be held and operated by hand, so that a patient may self-administer a drug as a cloud of fine particles.

Preferred embodiments of the present invention aim to provide nebulisers which may be relatively cheap and reliable to operate, and can be held and operated in the hand.

According to one aspect of the present invention, there is provided a dry powder nebuliser comprising:

a bore;

a piston arranged to slide in the bore;

a powder chamber;

an inlet port connecting the powder chamber with the bore;

an outlet port, spaced along the bore from the inlet port, for connecting the bore with an external environment; and

a one-way valve associated with said inlet port:

the arrangement being such that, upon moving the piston in the bore in a first direction, powder in the chamber is drawn into the bore through the inlet port and, upon moving the piston in the bore in a second, opposite

direction, powder drawn into the bore is entrained with air in the bore and forced past the piston to said outlet port, from where it exits the bore.

Preferably, said bore is rectilinear in extent.

Preferably, said bore and piston are substantially circular in cross-section.

Preferably, clearance is provided between the piston and bore, such that the piston may undergo slight movement within the bore, radially of the bore.

Preferably, said inlet port is formed in an end wall of the bore.

Preferably, said outlet port is formed at or adjacent one end of the bore.

Preferably, said outlet port is formed in a side wall of the bore.

Preferably, the bore is formed on its inside wall with a groove.

Preferably, said groove is formed as an annulus.

Preferably, said groove is part circular in cross-section.

Preferably, said outlet port opens into said groove.

Said powder chamber may be adapted to receive the powder in capsule form.

A nebuliser as above may include rupturing means for rupturing a capsule of powder in said powder chamber.

Preferably, said rupturing means includes a piercing means associated with an air inlet.

Preferably, said rupturing means includes a piercing means on said piston.

Preferably, said clearance is in the range 30μm to 100μm (0.0015 to 0.004 inches), measured radially of said bore when said piston is coaxial therewith.

Said external environment may comprise an inhalation chamber from which a user may inhale the powder.

The invention extends to a nebuliser according to any of the preceding aspects of the invention, together with a powder in the powder chamber, where said powder has a particle size in the range 1 to 5 microns.

According to another aspect of the present invention, there is provided a method of nebulising a powder, comprising the steps of placing powder in the powder chamber of a nebuliser according to any of the preceding aspects of the invention, and reciprocating the piston of the nebuliser to draw powder into the bore through the inlet port, and force

powder entrained with air in the bore past the piston to said outlet port, from where it exits the bore.

Preferably, said powder is a medicament and/or a vaccine.

For a better understanding of the invention, and to show how embodiments of the same may be carried into effect, reference will now be made, by way of example, to the accompanying diagrammatic drawings, in which:

Figure 1 is a side view of a hand-held nebuliser;

Figure 2 is an end view of the nebuliser of Figure 1; and

Figure 3 is a plan view of a motorised multi-cylinder nebuliser.

The nebuliser 1 shown in Figures 1 and 2 comprises a body 2 which defines a bore 3 in which a piston 4 is arranged to slide axially. The piston 4 may be retained in the bore 3 by an outer sleeve (not shown) or any other suitable means. Also defined in the body 2 is a powder chamber 5 which communicates with the bore 3 by way of an inlet port 6. A valve assembly 7 is detachably mounted in the body 2, and comprises a one-way valve for providing communication between the powder chamber 5 and ambient atmosphere, and a hollow probe 8 to pierce a capsule 9 within the powder chamber 5, and pass air into the capsule 9.

A spike 10 at one end of the piston 4 is arranged to pass through the inlet port 6 and also to puncture the capsule 9 in the powder chamber 5.

A return spring 11 is constrained between a head 12 of the piston 4 and a facing axial end of the body 2. The return spring 11 serves the dual purpose of returning the piston (to the left, as seen in Figure 1), and limiting the axial travel of the piston into the bore 3 (to the right, as seen in Figure 1), in order that the other axial end 13 of the piston 4 does not come into contact with the opposing end wall of the bore 3, but retains a predetermined clearance therewith.

An annular groove 14 is formed towards the open end of the bore 3, in an inner wall thereof, and communicates with an outlet port 15, which leads to the ambient atmosphere. A predetermined clearance is provided between the outer diameter of the piston 4 and the inner diameter of the bore 3. Adjacent the mouth of bore 3, there is provided an annular piston seal 16. By way of example, this may comprise an O-ring which is mounted in the inner wall of the piston 3.

The nebuliser 1 operates as follows.

The valve assembly 7 is removed from the body 2 (eg by unscrewing), to expose the powder chamber 5. A full, unbroken capsule 9 of powder is placed in the powder chamber 5. The valve assembly is then remounted in the body 2 (eg by screwing it into position) and, in this action, the hollow probe 8 pierces the respective end of the capsule 9.

The piston 4 is then urged towards the end of the bore 3 by means of pressure applied by the hand to the piston head 12. Towards the end of the axial travel of the piston 3, the spike 10 at the end of the piston 4 passes through the inlet port 6 and penetrates the side wall of the capsule 9 in the

powder chamber 5. The powder within the capsule 9 is therefore released and, upon the return stroke of the piston 4 (under the resilient bias of the return spring 11), air from the ambient atmosphere is drawn in through the one-way valve in the valve assembly 7, and passes through the hollow probe 8 to the inside of the capsule 9. The powder from within the capsule 9 then passes through the ruptured side wall of the capsule, through the inlet port 6 and into the bore 3. Upon the next compression stroke of the piston 4, the powder that has transferred from the powder chamber 5 into the bore 3 is entrained with air in the bore, and is forced at high speed through the radial clearance between the piston 4 and the bore 3, towards the outlet port 15. The powder, entrained with the air, enters the annular groove 14, and passes from there through the outlet port 15 to atmosphere.

An important feature of the embodiment of Figures 1 and 2 is that clearance is provided between the piston 4 and the bore 3. This allows a small amount of lateral movement of the piston 4 as it travels through the bore 3. Quite surprisingly, it has been found that this provides a much better action, in that the powder is dispensed in a much finer and more uniform cloud, than if the clearance is either minimal or large, or if means is provided for centering the piston 4 within the bore 3 as it slides therein. Such a latter arrangement may comprise, for example, 3 equi-spaced studs or ribs on the outside of the piston 4 or the inner wall of the bore 3, in order to provide true coaxial movement of the piston 4 within the bore 3. It has been found that, in such an arrangement, dispense of a fine powder is achieved to some degree.

However, much better results have been obtained with a distinct small clearance as mentioned above. It is thought that the clearance

provided between piston 4 and bore 3 may provide an irregular pumping effect with random and differing side wall contact between the piston 4 and bore 3. The piston 4 may chatter or rattle to some degree, within the bore 3. A combined shearing and pumping effect on the powder may be obtained.

By way of example, the powder particles may be manufactured to have a size of one to five microns, within the capsule 9. The diameter of the piston 4 and bore 3 may be of the order of 25mm, and the difference between the internal bore 3 and external diameter of the piston 4 may be of the order of 125 μm (0.005 inch), to give an average gap dimension of approximately 60μm (0.0025 inch). The stroke of the piston 4 may be of the order of 25mm.

The shallow, annular groove 14 may have a depth of around 25 μm (0.001 inch) and a width of around 4mm. The diameter of the outlet port 15 may be of the order of 4mm. If the outlet port 15 is too small, the flow will suffer. If it is too large, a less efficient dispersal of powder is achieved. Although the groove 14 is shown diagrammatically in Figure 1 as of rectangular cross-section, it is preferably rounded, to minimise accumulation of powder in corners.

The piston 4 and bore 3 need not be of circular cross-section. Alternative shapes could be adopted - eg oval, ellipsoid, rectangular, square, multi-faced, stellated, etc., to increase surface area with the possibility of increasing efficiency and/or compactness of the nebuliser.

Nebulisers such as 1 but of different dimensions may be constructed. For example, the diameters of the piston 4 and bore 3 may be in the range 5mm to 50mm. The difference in diameters in the bore 4 and the piston 3 may be in the range of 30μm to 100μm (0.0015 to 0.004 inch). The stroke of the piston 4 may be in the range of 5mm to 50mm. The depth of the groove 14 may be in the range 125μm (0.005 inch) to 0.5mm.

Larger, industrial size nebulisers may be produced, operating on a similar principle to that of the nebuliser 1. However, for a convenient, hand-held and hand-operated device, nebulisers having dimensions of the order given above, by way of example, may be particularly useful. The approximately 25mm bore and stroke have been found to give a satisfactory delivery.

If desired, a mechanism may be provided to cause the piston 4 to spin along its longitudinal axis as it travels along the bore 3. However, so far, this has not been found to be of particular benefit. The outer surface of the piston 4 and the inner surface of the bore 3 are preferably smooth, with a finish ranging from 16 finish to mirror finish. They may be provided with a regular injection moulding finish, as used in the medical industry.

The body and piston may be made of various suitable materials. For example, they may be made of an acrylic material, or a suitable injection moulded plastics. The nebuliser 1 may be made cheaply as a disposable product. Alternatively, for longer use, it may be made of more hard wearing material such as, for example, stainless steel or anodised aluminium. The latter may give particularly good results.

In Figure 1, the outlet port 15 is shown as communicating with ambient atmosphere. Where the powder is a drug, a patient may inhale the cloud of fine particles directly from the outlet port 15. Alternatively, the fine cloud of powder may be dispensed into a breathing chamber or vessel, from which a patient may inhale the drug.

In another variant, the fine cloud of powder may be dispensed into a further chamber where further pumping takes place. This may be by means of an additional piston, or a an additional piston portion formed integrally with or connected to the main piston 4.

Although the nebuliser 1 is shown as being hand-operated, by means of a force applied manually, positive driving means may be provided. For example, the piston 4 may be driven in either direction by a charge of compressed gas. A "latch and fire" mechanism may be provided, in which an energy store (eg a spring) is initially energised by a user, and released by pressing a trigger, in order to drive the piston 4 along the bore 3.

The powder to be dispensed need not be provided in the form of a capsule 9. Instead, it may be inserted in loose form into the powder chamber 5, by the intermediary of any other suitable packaging or conveying means - eg a bulk hopper or by shearing from a solid block of powder. It is known to supply a powdered drug in small blisters on a narrow strip of material. Such a strip of blisters may be fed through the powder chamber 5 so that each blister is presented in turn, in a manner similar to that used in toy "cap guns". This could provide a particularly convenient way of providing small, measured doses of a drug.

The inlet port 6 may be in a side wall rather than an end wall of the bore 3. The clearance maintained between the end of the piston 4 and the end wall of the bore 3 may prevent compression and therefore coagulation of the powder. Coagulation of powder can be a particular problem in dry powder nebulisers.

Instead of the outlet port 15, the powder may be allowed to escape through an open axial end of the bore 3 - for example, into an inhalation chamber. An outlet port may be provided in an axial end wall of the body 2, rather than extending radially of the body 2.

In the variant shown in Figure 3, a four-cylinder nebuliser 30 is shown. In this embodiment, 4 nebulisers 31, each generally similar in mode of operation to the nebuliser 1 of Figure 1, are arranged radially, with pistons driven by connecting rods 32 that are connected to a central rotary crank 33 which may be power driven - for example, by means of an electric motor or actuator. Such a nebuliser could dispense drugs in much larger quantities, and/or continuously. Powder from capsules 39 is nebulised into fines which are transferred via passages 35 into a secondary chamber (not shown).

More generally, nebulisers having two or more cylinders may be provided.

In general, tests have shown that a nebuliser such as 1 can provide a very simple device that is able to convert a large percentage of encapsulated powder (eg sodium cromoglycate, salbutamol, for inhalation) to a desired form for maximum effect. Not only does the device generate an abundant

supply of fines, it is not reliant upon the lung power of the user, as are so many known inhalers. Fines down to one to five microns have been achieved, which is a particularly desirable particle size for an inhaler.

The term "air" is used conveniently in this specification to denote a gaseous ambient atmosphere and, as will be readily understood by those skilled in the art, is to be interpreted to include any other gaseous atmosphere other than air.

In this specification, the verb "comprise" has its normal dictionary meaning, to denote non-exclusive inclusion. That is, use of the word "comprise" (or any of its derivatives) to include one feature or more, does not exclude the possibility of also including further features.

The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference.

All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

Each feature disclosed in this specification (including any accompanying claims, abstract and drawings), may be replaced by alternative

features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar features.

The invention is not restricted to the details of the foregoing embodiment(s). The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

CLAIMS

1. A dry powder nebuliser comprising:

a bore;

a piston arranged to slide in the bore;

a powder chamber;

an inlet port connecting the powder chamber with the bore;

an outlet port, spaced along the bore from the inlet port, for connecting the bore with an external environment; and

a one-way valve associated with said inlet port:

the arrangement being such that, upon moving the piston in the bore in a first direction, powder in the chamber is drawn into the bore through the inlet port and, upon moving the piston in the bore in a second, opposite direction, powder drawn into the bore is entrained with air in the bore and forced past the piston to said outlet port, from where it exits the bore.

2. A nebuliser according to claim 1, wherein said bore is rectilinear in extent.

3. A nebuliser according to claim 1 or 2, wherein said bore and piston are substantially circular in cross-section.

4. A nebuliser according to claim 1, 2 or 3, wherein clearance is provided between the piston and bore, such that the piston may undergo slight movement within the bore, radially of the bore.

5. A nebuliser according to any of the preceding claims, wherein said inlet port is formed in an end wall of the bore.

6. A nebuliser according to any of the preceding claims, wherein said outlet port is formed at or adjacent one end of the bore.

7. A nebuliser according to any of the preceding claims, wherein said outlet port is formed in a side wall of the bore.

8. A nebuliser according to any of the preceding claims, wherein the bore is formed on its inside wall with a groove.

9. A nebuliser according to claim 8, wherein said groove is formed as an annulus.

10. A nebuliser according to claim 8 or 9, wherein said groove is part circular in cross-section.

11. A nebuliser according to claim 7, together with claim 8, 9 or 10, wherein said outlet port opens into said groove.

12. A nebuliser according to claim, wherein said powder chamber is adapted to receive the powder in capsule form.

13. A nebuliser according to claim 12, including rupturing means for rupturing a capsule of powder in said powder chamber.

14. A nebuliser according to claim 13, wherein said rupturing means includes a piercing means associated with an air inlet.

15. A nebuliser according to claim 13 or 14, wherein said rupturing means includes a piercing means on said piston.

16. A nebuliser according to claim 14 or to any of claims 5 to 15 as appendant thereto, wherein said clearance is in the range 30μm to 100μm (0.0015 to 0.004 inches), measured radially of said bore when said piston is coaxial therewith.

17. A nebuliser according to any of the preceding claims, wherein said external environment comprises an inhalation chamber from which a user may inhale the powder.

18. A nebuliser substantially as hereinbefore described with reference to the accompanying drawings.

19. A nebuliser according to any of the preceding claims, together with a powder in the powder chamber, where said powder has a particle size in the range 1 to 5 microns.

20. A method of nebulising a powder, comprising the steps of placing powder in the powder chamber of a nebuliser according to any of the preceding claims, and reciprocating the piston of the nebuliser to draw powder into the bore through the inlet port, and force powder entrained with air in the bore past the piston to said outlet port, from where it exits the bore.

21. A method substantially as hereinbefore described with reference to the accompanying drawings.

22. A nebuliser or method according to claim 19, 20 or 21, wherein said powder is a medicament and/or a vaccine.

The Patent Office

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Application No: GB 9805088.3 **Examiner:** L.V.Thomas
Claims searched: 1-22 **Date of search:** 24 June 1998

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

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Int Cl (Ed.6): A61M 11/00, 11/02, 13/00, 15/00

Other: Online: WPI, CLAIMS

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
A	WO 92/10229 A1 (NORTON HEALTHCARE) see p.9 l.14 - p.11 l.12	1

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.